510(K) Summary:

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October 25, 2012

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92

1. Submitter Information:

a. Applicant:

Bionix Development Corporation

5154 Enterprise Blvd.

Toledo, Ohio 43612

b. Contact:

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Vice President, New Product Development

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2. Device Name:

a. Trade Name:

Little Angels Swaddling Blanket

b. Common Name:

Swaddling blanket for use with neonatal phototherapy systems

c. Classification Name: Blanket, Neonatal Phototherapy

(Per CFR section 880.5700)

3. Intended Use:

The Little Angels Swaddling Blanket is intended to be used as an adjunct to neonatal phototherapy systems used for the treatment of neonatal hyperbilirubinemia in the clinical or home setting.

4. Substantial Equivalence Device(s):

The Little Angels Swaddling Blanket is similar in composition and function to the following device used as an adjunct to current neonatal phototherapy systems used to treat neonatal hyperbilirubinemia.

a. Disposable fiber optic pad covers use with the BiliSoft Phototherapy System manufactured and legally marketed by Lumitex, Inc., Strongsville, OH. This device is listed under regulation number 880.5700, Unit, Neonatal Phototherapy, and is classified as a Class II device. This device has been cleared by the FDA under K053568.

5. Device Description:

The Little Angels Swaddling Blanket is intended to be used as an adjunct to neonatal phototherapy systems used for the treatment of neonatal hyperbilirubinemia in the clinical or home setting. The Little Angels Swaddling Blanket is similar in composition and function to other devices used as adjuncts to current neonatal phototherapy systems used to treat neonatal hyperbilirubinemia.

The Little Angels Swaddling Blanket is comprised of a sheet of spun bond polypropylene material that is die-cut and heat welded in a pattern that allows an infant undergoing phototherapy for hyperbilirubinemia to be tightly swaddled in a fashion such that only a single layer of material is ever interposed between the infant and the phototherapy source.

Spun bond polypropylene is a commonly used fabric in medical products and garments. Spun bond polypropylene is non-irritating to the skin, soft, and has a good drape that allows it to easily conform to body contours. Spun bond polypropylene is available in different fabric weights, depending on the tightness of the weave and fabric density. Light-weight spun bond polypropylene fabric is used in the Little Angels Swaddling Blanket to ensure maximum light transmittance from the phototherapy source to the patient's skin. (See section on "Bench Testing".)

In use, an infant undergoing phototherapy for hyperbilirubinemia is first laid atop the Little Angels Swaddling Blanket, and the blanket is then folded around the infant in a prescribed fashion that ensures the infant is tightly swaddled and that only a single layer of fabric lies between the phototherapy source and the infant's skin. When an overhead phototherapy source is used, the swaddled infant is then placed under the light source in the usual fashion in order to receive the phototherapy treatment. The Little Angels Swaddling Blanket also has a pocket formed in its rear panel (under the infant). If a light emitting pad type phototherapy source is to be used, the light emitting pad is placed in this pocket and phototherapy is administered to the swaddled infant in the usual fashion. Also, double phototherapy can be administered to an infant swaddled using the Little Angels Swaddling Blanket by combining an overhead phototherapy source together with a light emitting pad type phototherapy source, each used as described above.

6. Comparison to Predicate Devices:

The following table summarizes the comparison of Bionix Development Corporation Little Angel Swaddling Blanket to the predicate device:

Attribute	BiliSoft Phototherapy System Disposable Pad Covers (Lumitex, Inc.)	Little Angels Swaddling Blanket (Bionix)	
Intended Use	Adjunct to neonatal phototherapy systems (cover for light emitting pad)	Adjunct to neonetal phototherapy systems (swaddling blanket)	
Composition	Spun bond polyester	Spun bond polyester	
ight Transmittance	59% (see bench testing)	>90% (see bench testing)	
Material Weight	118 g/m² (see bench testing)	15.29 g/m² (published company data)	
Single Patient Use	Yes	Yes	
ocket for Fiberoptic hototherapy Source	Yes	Yes	
Material Between Infant and hototherapy Source	Single layer	Single layer	
Skin Contact Duration	Less than 24 hours	Less than 24 hours	
Swaddles Infant	No	Yas	

Table 1
Comparison of Substantial Equivalence

7. Bench Testing:

Samples of the spun bond polypropylene material used in the construction of the of the Little Angels Swaddling Blanket from Bionix, along with the spun bond polypropylene material used in the manufacture of the BiliSoft disposable pad covers, were tested for light transmittance properties using a light meter as described in the section titled "Bench Testing" of this document. Fabric weights of the materials used in each device were also determined. The results of these testing are summarized in the following tables:

Phototherapy Ught Source	Material S Tested	(no material)	Material Tass (E	Material Test /2	Material Text (Average)	Tonnellish
GE Giraffe SPOT PT	Little Angels Blanket (Bionix)	36.9 µw/cm2/nm	34.3 μw/cm2/nm	33.4 μw/cm2/nm	33.9 μw/cm2/nm	91.7 %
Drager PT 4000	Little Angels Blanket (Blonix)	30.4 μw/cm2/nm	27.4 μw/cm2/nm	27.3 μw/cm2/nm	27.4 μw/cm2/nm	90.0 %
GE Giraffe SPOT PT LITE	Billisoft Cover (Lumitex)	35.3 μw/cm2/nm	19.4 μw/cm2/nm	22.4 μw/cm2/nm	20.9 μw/cm2/nm	59.2 %
Drager PT 4000	Billisoft Cover (Lumitex)	31.2 μw/cm2/nm	18.0 μw/cm2/nm	18.7 μw/cm2/nm	18.4 μw/cm2/nm	58.8%

Table 2
Bench Test Results
Light Transmittance Testing

Device	Manufacturer	Maximum Light Transmittance (%)	Fabric Weight
BiliSoft Phototherapy System Disposable Pad Covers	Lumitex, Inc.	59.21 %	118 g/m²
Little Angels Swaddling Blanket	Bionix	≥90 %	15.29 g/m²

Table 3
Bench Test Results
Light Transmittance and Material Weight

8. Clinical Testing:

No clinical testing was performed on the Little Angels Swaddling Blanket from Bionix Development Corporation.

9. Conclusion:

The similarity of composition, performance, and features indicate that the Little Angels Swaddling Blanket from Bionix Development Corporation will perform as well as the legally marketed disposable covers used with the BiliSoft Phototherapy System by Lumitex, Inc. for the intended use as an adjunct to neonatal phototherapy systems used for the treatment of neonatal hyperbilirubinemia.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

--March-7, 2013 ---- --

James Huttner, M.S., Ph.D. Vice President Bionix Development Corporation 5154 Enterprise Boulevard TOLEDO OH 43612

Re: K123411

Trade/Device Name: Blanket, Neonatal Phototherapy

Regulation Number: 21 CFR 880.5700

Regulation Name: Neonatal Phototherapy Unit

Regulatory Class: II Product Code: PDH Dated: January 9, 2913 Received: January 23, 2013

Dear Dr. Huttner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply—with all the Act's requirements, including, but not limited to:-registration and-listing-(21-CFR——Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement:

510(k) Number (if known): K123411

Device Name: Blanket, Neonatal Phototherapy

Indications for Use:

The Little Angels Swaddling Blanket developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used as an adjunct to neonatal phototherapy systems used for the treatment of neonatal hyperbilirubinemia in the clinical or home setting.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ______(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Division Sign-Off)	Page 1 of 1

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Infection Control, Dental Devices

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